

REMARKS

Claims 38-40, 42 and 44 stand rejected by the August 26, 2002, Office Action. This Amendment amends claims 38, 40 and 42. Reexamination and reconsideration are respectfully requested.

Claim Rejections Under 35 USC § 102(e)

Claims 38-40, 42 and 44 stand rejected under 35 USC § 102(e), as being anticipated by Pflueger et al., U.S. Pat. No. 5,304,115, issued April 19, 1994 (hereinafter "Pflueger"). Applicants respectfully traverse this rejection.

Applicants' independent claim 38 recites, "A device for insertion into a body lumen useful for dissolution of obstructive material, the device comprising: a source of *low-frequency* mechanical motion; and an elongate vibratory motion catheter having a proximal portion, a distal portion, and a longitudinal axis therebetween, wherein said proximal portion is matingly engageable with the source of mechanical motion, wherein said source of mechanical motion is configured to provide low-frequency vibrational motion to the vibratory motion catheter, said *low-frequency* vibrational motion including rotational motion about the longitudinal axis and at least one of translational motion and oscillatory motion." (Emphasis added.)

Independent claim 42 recites, "A method of dissolution of obstructive material in a body lumen of a patient comprising: providing a source of *low-frequency* mechanical motion coupled to an elongate vibratory motion catheter having a proximal portion, a distal portion, and a longitudinal axis therebetween; inserting said vibratory motion catheter into the body lumen of the patient such that said source of mechanical motion remains outside the patient's body; and activating said source of mechanical motion such that said source of mechanical motion causes *low-frequency* vibration of said vibratory motion catheter along said longitudinal axis, said vibration including rotational motion about the longitudinal axis and at least one of translational and oscillatory motion and said vibration resulting in a mixing action within said body lumen." (Emphasis added.)

Each of Applicants' amended independent claims 38 and 42 includes, "a source of low-frequency mechanical motion" and either "low-frequency vibrational motion" or "low-

frequency vibration." Amended dependent claim 40 also recites "low frequency vibrational motion." Support for the amendments to claims 38, 40 and 42 may be found in the originally filed specification, and no new matter has been introduced. The phrase "low frequency" is defined in the specification as about 1-5000 Hz (for example, on page 4, line 33).

Pflueger generally discloses an ultrasonic angioplasty device including an ultrasound transmission member or wire 20 attached to an ultrasound generator 24 for conveying ultrasound energy along the wire 20. The wire 20 then vibrates within the lumen 14, 14a of the catheter body 12, 12a, to produce cavitation within a blood vessel. Pflueger does not disclose, teach or suggest low-frequency vibrational motion or a source thereof. Instead, Pflueger teaches only devices for applying ultrasound energy through an ultrasound transmission member 20 to ablate atherosclerotic plaque. (See, e.g., column 9, lines 36-46). Although Pflueger does not specifically describe a range of frequencies in which his ultrasound catheter operates, ultrasound by definition has a frequency of greater than 20,000 Hz.

Therefore, Applicants submit that each and every element of independent claims 38 and 42 are not disclosed or taught by Pflueger. Accordingly, independent claims 38 and 42 (and claims 39-40 and 44, each of which variously depends from claim 38 or 42) are not anticipated by Pflueger, and Applicants respectfully request the withdrawal of the rejection of claims 38-40, 42 and 44 under 35 USC § 102(e).

Furthermore, Applicants submit that their invention as described in claims 38-40, 42 and 44 would not have been obvious under 35 U.S.C. § 103(a) in view of Pflueger. Because Pflueger's device relies on high-frequency, ultrasonic vibration, it would not have been obvious to provide low-frequency vibrational motion or a source thereof as part of Pflueger's invention. Such low-frequency vibration has been found to be advantageous in devices and methods of the Applicants' invention but would not have been obvious for use with an inherently high-frequency ultrasound device.


CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Attached is a marked up version of the changes made to the specification and claims by the current amendment as Appendix A: "VERSION WITH MARKINGS TO SHOW CHANGES MADE." A clean copy of the claims is further attached as Appendix B: "CLEAN COPY OF PENDING CLAIMS."

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650/ 752-2457.

Respectfully submitted,



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APPENDIX A
VERSION WITH MARKINGS TO SHOW CHANGES MADE

38. (Twice amended) A device for insertion into a body lumen useful for dissolution of obstructive material, the device comprising:

a source of low-frequency mechanical motion; and

an elongate vibratory motion catheter having a proximal portion, a distal portion, and a longitudinal axis therebetween, wherein said proximal portion is matingly engageable with the source of mechanical motion,

wherein said source of mechanical motion is configured to provide low-frequency vibrational motion to the vibratory motion catheter, said low-frequency vibrational motion including rotational motion about the longitudinal axis and at least one of translational motion and oscillatory motion.

40. (Twice amended) A device of Claim 38 wherein said source of mechanical motion is configured to provide said low-frequency vibrational motion to said elongate vibratory motion catheter such that said vibrational motion is greater near the distal end of said elongate vibratory motion catheter than at the proximal end of said elongate vibratory motion catheter.

42. (Twice amended) A method of dissolution of obstructive material in a body lumen of a patient comprising:

providing a source of low-frequency mechanical motion coupled to an elongate vibratory motion catheter having a proximal portion, a distal portion, and a longitudinal axis therebetween;

inserting said vibratory motion catheter into the body lumen of the patient such that said source of mechanical motion remains outside the patient's body; and

activating said source of mechanical motion such that said source of mechanical motion causes low-frequency vibration of said vibratory motion catheter along said longitudinal axis, said vibration including rotational motion about the longitudinal axis and at least one of

translational and oscillatory motion and said vibration resulting in a mixing action within said body lumen.

Claim 43 previously canceled.